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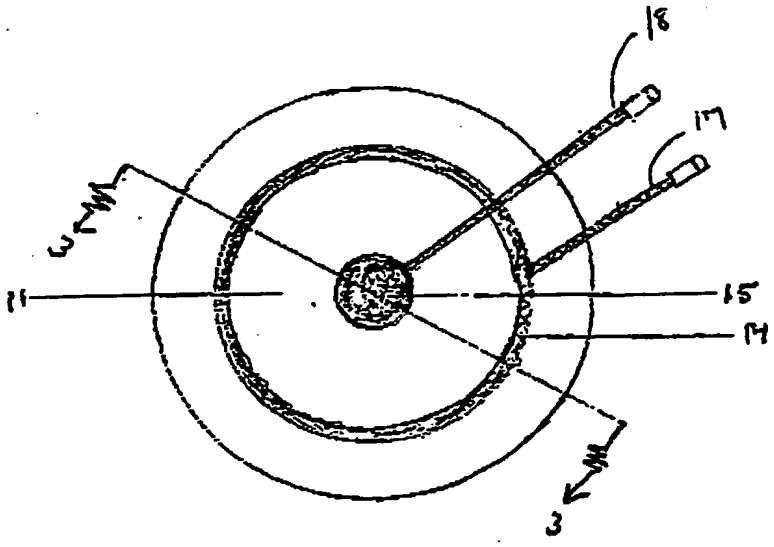

(57) Abstract

An electrode configuration involving a single bipolar electrode, rather than a pair of conventional electrodes, for use on the surface of the skin. The skin surface electrode is more convenient and improves the performance of electrical medical treatments such as Transcutaneous Electrical Nerve Stimulation, electrotherapy, and monitoring. The electrode allows improved localization and focusing treatment on a specific area.

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TITLE: BIPOLAR CONCENTRIC ELECTRODE FOR MEDICAL TREATMENT

SPECIFICATION

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates to an electrode configuration which features improved transmission of current to or from body tissues through electrical contact with the skin.

The configured electrode of this invention leads to improved performance of electrical medical treatments such as those conducted using Transcutaneous Electrical Nerve Stimulation (TENS) as well as with other electrotherapy devices. The configured electrode can also usefully be employed for other uses such as monitoring.

2. Background of the Invention

Electrodes for medical use, such as use in electrotherapy, consist principally of means for letting current flow into or out of the conductors and of means of distributing the current throughout. The conductive portion of the electrotherapy electrode can be made from a mesh of conducting wire metal, such as stainless steel, and the like, imbedded in various materials such as conductive agar gels and synthetic polymers. The conductive polymer can be made up of aqueous gel-like polymers containing approximately 95.5% water, 4% polyethylene oxide, and 0.5% electrolytic salt. The electrolytic salt is a conductive gel capable of adhering to the skin. It is possible to use natural rubber with

aqueous polyethylene oxide gels to form an electrotherapy electrode. As disclosed in U.S. Pat. No 4,893,626 such material constitutes a good conductive medium with good adhesion to the skin.

While there are numerous patents relating to medical electrodes, they are concerned primarily with improving the electrode through the use of various materials, including conducting, nonconducting, aqueous, and nonaqueous materials, rather than with improving the electrode geometry. Examples of such attempts include: U.S. Patent Nos. 3,357,930; 3,911,906; 3,994,302; 3,998,215; 4,008,721; 4,094,822; 4,066,078; 4,125,110; 4,273,135; and 4,893,626.

SUMMARY OF THE INVENTION

The present invention relates to a novel configuration skin surface electrode which is preferably multipolar, most preferably bipolar, having concentric conductors. The electrode can be applied to the skin surface for purposes of electrical medical treatment. The novel electrode makes it possible to use a single electrode in lieu of a pair of electrodes presently required in the case of conventional electrodes. The single concentric electrode of this invention gives improved results over those obtained using a pair of conventional electrodes.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a bottom view of a circular insulated plate showing the outer and central conductors.

Fig. 2 shows the device as in Fig. 1 with the conductive material applied to the conductors.

Fig. 3 is a cross sectional view taken along the line 3-3 of the electrode shown in Fig. 2.

Fig. 4 shows the projected electrical field outside the electrode.

DESCRIPTION OF THE PREFERRED EMBODIMENT

The electrode of this invention can be used in one of two basic modes.

(1) Differential Measurement. A first lead 17 can be connected to an outer conductor 12, while a second lead 18 is connected to a central conductor 13. The lead of a ground electrode, not related to the bipolar electrode of this invention, but associated with the treatment or monitoring device, is connected to the left leg of the patient as would be done in a conventional system using a pair of electrodes.

(2) Non-Differential Measurement. A first lead 17 and the ground lead, are connected to the outer conductor 12, and the second lead 18 is connected to the central conductor 13. In this case a single electrode of the present invention is used instead of a pair of conventional electrodes. The optimal or preferable location for the placement of the electrode is above the apex of the heart. Such placement would tend to yield an optimal signal to noise ratio. The device can, of course, be located at other points on the body.

A circular concentric bipolar configuration is preferred for the electrode of this invention. The electrode may consist of any suitable material, such as the materials used in conventional electrodes. For example, the electrode can be made of materials described in U.S. Patent Application Serial No. 893,626 filed January 16, 1990, which is incorporated herein by reference as if fully set forth herein.

The electrode of this invention is disposed on an insulator plate 11 made of an insulating material such as natural rubber. A central circular conductor 13 made of

aluminum is located on the insulator plate 11. An outer annular conductor ring 12 is also made of aluminum. The conductor may be made from any type of appropriate material, such as carbonized rubber film.

Fig. 3 showing the electrode in cross section indicates the two conductors 13 and 12 as being somewhat raised from the plane of the insulator plate 11. Typically, the insulator plate 11 would have a thickness of approximately 1 mm, while the two conductors 13 and 11 would project from the surface of the insulator plate 11 for a distance of approximately 0.1 mm. The conducting gel 14 and 15 would normally project from the insulator plate 11 for a distance of approximately 0.2 mm. These dimensions are only exemplary and other configurations are workable, such as, for example, where the conductor plates 13 and 11 are embedded in grooves cut out of the insulator plate 11 such as their top surface is below that of the insulator plate 11. While such configurations would be workable, it would be preferred to have the two conductor be approximately flush with the surface of the insulator plate so as to reduce the possibility of damaging or irritating the skin with the electrode.

On the central conductor 13 is placed a conducting gel 15, made of aqueous polyethylene oxide, known by its commercial name Stratum, a product of NAPERA Chemical Company, Inc., a subsidiary of A.G. Schering (West Germany). The conducting gel 14 placed on the outer conductor ring 12 is made of the same conducting gel. Lead wire connectors made of copper 17 and 18 connect the two conductors to external devices, such as a TENS unit.

The preferred diameter of the insulator plate 11 is from 12 to 90 mm, most preferably around 54 mm. The area of the conducting gel 14 covering the outer conductor

ring is from 12 to 480 mm^2, most preferably around 122 mm^2.

The central diameter of the conducting gel 15 covering the central conductor 13 is from 1 to 20 mm, most preferably around 12.4 mm. The area of the central conducting gel 15 or central conductor 13 is from 0.785 to 314 mm^2, most preferably around 122 mm^2. For best results the central conducting gel 15 should completely cover the central conductor 13 but can also cover a larger area.

The mean diameter of the outer conductor 12 is from 10 to 80 mm, most preferably around 44 mm. For best results the outer conducting gel 14 should completely cover the outer conductor 12 but can also cover a larger area. The amount of conducting medium used should be sufficient to cover the area of the skin to be treated and to detect sufficient current for diagnostic purposes. It is preferable that the total area of the central conductive gel 15 be equal to the total area of the outer conducting gel 14.

A bipolar circular electrode having two concentric conductors according to the present invention was tested and compared with a pair of conventional electrodes. Details of this testing and comparisons are set forth below. Some of the advantages found for the electrode of the present invention over a pair of conventional electrodes for electrotherapy applications such as TENS, for monitoring, and for a variety of other electrical medical treatments are as follows:

(1) The electrode of this invention is more economical, both from a materials and from an operational point of view, since only one electrode, rather than two electrodes is required. Various medical monitoring functions, such as heart beat monitoring, are more conveniently performed with one electrode than with a

pair of electrodes. The concentric electrode of this invention is more convenient and has better performance in electrical medical treatment and uses, such as TENS.

(2) Use of a single electrode facilitates the localization of specific treatments and allows the affected tissue to be confined to a well-defined region. The electrical field created by the electrode of this invention is more focused, which enables deeper and more precise electrical penetration. It is easier to localize the specific area of treatment, since only a single electrode is involved and the electrical field is more uniform, homogenous, and symmetrical.

(3) The electrode of this invention achieves the desired results while producing lower current output than conventional electrodes.

(4) The electrical field which is generated by the concentric electrode of this invention is more uniform, denser, and more symmetric than that produced by a pair of conventional electrodes. Since the conductive material is very close to the conductor, the current is more uniformly distributed throughout the conductive zones. Fig. 4 shows the approximate disposition of the electric field in the tissue when the electrode of this invention is activated while placed against the skin.

(5) The area of the conductive material is relatively small.

(6) The concentric electrode of this invention displays less electrode resistance variation than do conventional electrodes, especially during movement.

(7) The electrode of this invention improves electrode performance regardless of the material of construction.

(8) The electrode of the present invention provides better results when used for electrocardiogram (EKG) beat-to-beat monitoring. It provides clearer and more

accurate signals and avoids interferences. It is more comfortable than conventional electrodes.

Comparisons were made between the electrode of the present invention and the electrode as described in U.S. Patent No. 4,893,626. Both electrodes have about the same area and are made of the same material. Both were connected to the same TENS unit and the following settings were used:

frequency: 15 pulses/sec.
pulse duration: 0.2 millisecond
rate of repetition: 2 sec.

The electrode taught in U.S. Patent No. 4,893,626 was placed adjacent the median and radial nerves or motor point of Flexor Profundus Digitorium. The second conventional electrode was placed adjacent the Deltoid or the Gluteus. The location of the electrode of the present invention was adjacent the median and radial nerves or motor point of Flexor Profundus Digitorium. This location is the preferred placement for use with the bipolar concentric electrode of the present invention.

The five tests of the reaction to contraction of the middle finger and ring finger using a conventional pair of electrodes yielded an average of approximately 40 milliampere peak current. Using the single bipolar concentric electrode of the present invention, an average of only 30 milliampere peak current was obtained. It is concluded that the electrode of the present invention generates lower current outputs and thus provides a more efficient, more highly focused, electrical field.

Tests were conducted to measure the extent of the electrical field using the electrode of this invention compared to using conventional electrodes. In each case, raw meat was used to simulate human tissue.

A coaxial needle of 1 mm diameter was inserted into the raw meat at various points to detect the electric

field. Tests were conducted at two depths, 2 mm and 15 mm. Four measuring points were used. The placement of the four points are indicated in Figure 1 as 21, 22, 23 and 24. The surface of the coaxial needle was completely covered with isolating paint except for the portion within 2 mm of the needle point. The raw meat was stimulated by electrical pulses of 40 milliamp peak current and 100 microsecond pulse width. The results in each case representing an average of ten measurements are as follows:

Concentric Electrode of Present Invention
Potential Differences

Point/Potential	2 mm Depth (mV)	15 mm Depth (mV)
21	0-1	0-0.5
22	18	24
23	15	20
24	19	25

Conventional Electrode Potential Differences

Point/Potential	2 mm Depth (mV)	15 mm Depth (mV)
21	7	6
22	9	8
23	9	11
24	14	13

As can be seen, the comparison test clearly demonstrates the differences in the indirect current density between the concentric electrode of the present invention and conventional electrodes. The current density of the concentric electrode of the present invention is approximately twice as large as that of the conventional type of electrode for points 22, 23 and 24 located in the tissue directly below the electrode of this invention. By contrast, the number 21 testing point

shows a very low value for the concentric electrical indicating that this testing point is effectively outside of the electrical field. This clearly indicates that the electrode of this invention creates a more focused electrical field than that produced by conventional electrodes.

It is seen that the present invention and the embodiments disclosed herein are well adapted to carry out the objectives and obtain the ends set forth at the outset. Certain changes can be made in the method without departing from the spirit and the scope of this invention. It is realized that changes are possible and it is further intended that each element recited in any of the following claims is to be understood as referring to all equivalent elements for accomplishing substantially the same results in substantially the same or equivalent manner. It is intended to cover the invention broadly in whatever form its principles may be utilized. The present invention is, therefore, well adapted to carry out the objects and obtain the ends and advantages mentioned, as well as others inherent therein.

Those skilled in the art may find many variations and adaptations thereof, and all such variations and adaptations, falling within the true scope and spirit of applicant's invention, are intended to be covered thereby.

WHAT IS CLAIMED IS:

1. An electrode for use on the skin surface, comprising:

an insulator plate made of insulating material and having a bottom surface;

a central conductor covering an area near the center of the bottom surface of the insulator plate;

an outer conductor covering an area of the bottom surface of the plate outside of and surrounding the central conductor;

means for electrically connecting the central conductor to receive electricity; and

means for electrically connecting the outer conductor to receive electricity.

2. The electrode of claim 1 wherein the central conductor is substantially circular in shape.

3. The electrode of claim 2 wherein the outer conductor is substantially annular in shape and is substantially concentric with the central conductor.

4. The electrode of claim 3 wherein the outer conductor is substantially annular in shape.

5. The electrode of claim 4 wherein the diameter of the central conductor is from 1 to 20 mm.

6. The electrode of claim 4 wherein the mean diameter of the outer conductor is from 10 to 80 mm.

7. The electrode of claim 4 wherein the central conductor and the outer conductor have areas which are substantially equal.

8. The electrode of claim 1 further comprising a layer of conductive gel covering the central conductor and the outer conductor.

9. The electrode of claim 2 further comprising a layer of conductive gel covering the central conductor and the outer conductor.

10. The electrode of claim 3 further comprising a layer of conductive gel covering the central conductor and the outer conductor.

11. The electrode of claim 4 further comprising a layer of conductive gel covering the central conductor and the outer conductor.

12. The electrode of claim 5 further comprising a layer of conductive gel covering the central conductor and the outer conductor.

13. The electrode of claim 6 further comprising a layer of conductive gel covering the central conductor and the outer conductor.

14. The electrode of claim 7 further comprising a layer of conductive gel covering the central conductor and the outer conductor.

FIG. 1

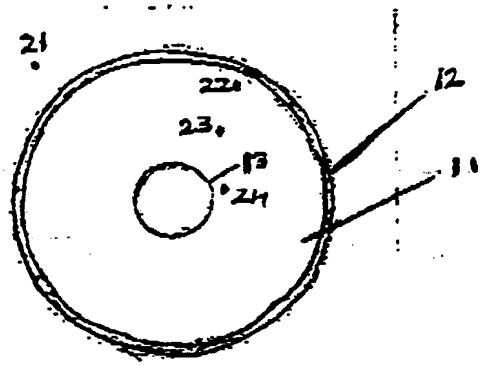


FIG. 2

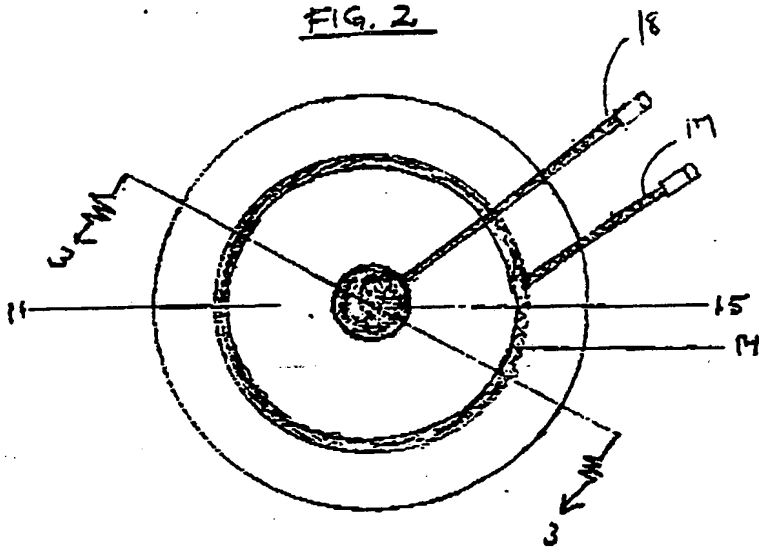


FIG. 3

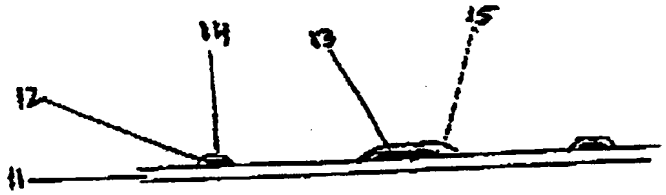
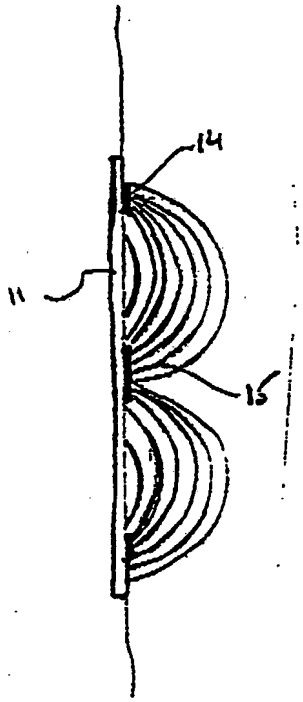


FIG. 4



INTERNATIONAL SEARCH REPORT

International Application No PCT/EP 91/01083

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all)[6]

According to International Patent Classification (IPC) or to both National Classification and IPC

Int.Cl. 5 A61N1/04

II. FIELDS SEARCHED

Minimum Documentation Searched[7]

Classification System	Classification Symbols
Int.Cl. 5	A61N

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched[8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT[9]

Category °	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No.[13]
X	FR,A,2 509 182 (KABUSHIKIKAISYA ADVANCE) January 14, 1982	1;8
A	see page 3, line 13 - page 4, line 27	9-14

X	FR,E,65 169 (DUFLOT) January 27, 1956 see the whole document	1-4

X	US,A,3 987 795 (MORRISON) October 26, 1976 see column 7, line 37 - line 59 see column 5, line 47 - line 66	1-4,7

X	DE,C,394 385 (LEWIN) January 7, 1923 see the whole document	1-4

A	US,A,4 125 110 (HYMES) November 14, 1978 cited in the application see column 4, line 7 - line 14	5,6

° Special categories of cited documents : [10]

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IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
02 OCTOBER 1991	16 OCT 1991
International Searching Authority	**Signature of Authorized Officer**
EUROPEAN PATENT OFFICE	LEMERCIER D.L.L.

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO.

EP 9101083
SA 48106

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on
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